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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,739

Applicant(s)

ROBERTSON ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2001 and 08 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 20-22, 30-33, 50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-4, 20-22, 30-33, 50, and 51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to method of detecting cancer related marker protein, classified in class 435, subclass 7.23.
- II. Claims 20-22, and 50, drawn to diagnostic reagents, classified in class 530, subclass 387.3.
- III. Claims 30-33, 50, 51, drawn to cell line capable of producing autoantibodies against breast cancers, classified in class 435, subclass 69.1.
- IV. Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with lymphomas, classified in class 435, subclass 69.1.
- V. Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with leukemias, classified in class 435, subclass 69.1.
- VI. Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with colorectal cancers, classified in class 435, subclass 69.1.
- ~~VI.~~ ~~VII.~~ Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with lung cancer, classified in class 435, subclass 69.1.
- ~~VIII.~~ ~~VII.~~ Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with pancreatic cancers classified in class 435, subclass 69.1.
- ~~IX.~~ ~~VIII.~~ Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with prostate cancers, classified in class 435, subclass 69.1.

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- X ~~IX~~. Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with cervical cancers, classified in class 435, subclass 69.1.
- XI ~~X~~. Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with lymphomas, classified in class 435, subclass 69.1.
- XII ~~X~~. Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with ovarian cancers, classified in class 435, subclass 69.1.
- XIII ~~XII~~. Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with endometrial cancers, classified in class 435, subclass 69.1.
- XIV ~~XIII~~. Claims 30-32, 50, 51, drawn to cell line capable of producing autoantibodies against an epitope of marker protein associated with skin cancers, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as purifying a cancer marker.

Inventions III-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are cell lines producing different products with different binding specificities and/or different molecular structures.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. The search required

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for each of the above inventions is not coextensive with regard to the literature and the sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, restriction for examination purposes is proper.

Groups I-XIII contain a plurality of disclosed patentably distinct species:

- MUC1,
- BRCA1,
- BRCA2,
- p53,
- c-myc,
- c-erb-beta2
- Ras

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

February 24, 2003


SHEELA HUFF
PRIMARY EXAMINER